



CardinalHealth

Cardinal Health
1430 Waukegan Road
McGaw Park, Illinois 60085-6787
847.578.6610
FAX: 847.785.2506

K090211

JUL - 1 2009

SMDA REQUIREMENTS

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Inflatable Bone Tamp**

Sponsor:	Cardinal Health 1430 Waukegan Road MPKB McGaw Park, IL 60085
Regulatory Affairs: Contact	Sharon Nichols
Telephone:	(847) 578-6610
Date Summary Prepared:	January 2009
Common Name:	Inflatable Bone Tamp
Regulation Description:	Primary - Arthroscope Secondary - Cement, bone, vertebroplasty
Device Class and Regulation Number:	Class II per 21CFR §888.1100, Procode HRX: Class II per 21CFR §888.3027, Procode NDN:
Predicate Devices:	Kyphx Inflatable Bone Tamp, K041454, K981251 Radiopaque Bone Cement, K043518
Description:	The Inflatable Bone Tamp (IBT) was designed for use in Balloon kyphoplasty. The balloon serves to create a cavity in the vertebral body, thereby reducing the fracture and preventing cement leakage,

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while still allowing for cement interdigitation. The balloon catheter is the functional part of the device that creates a cavity and reduces the fracture. The balloon catheter provides a conduit through which the physician can inflate the balloon at the distal end of the catheter. The wire stiffener provides stiffness to the balloon catheter to facilitate insertion through the access cannula

Intended Use:

Intended for the reduction and fixation of fractures in cancellous bone in the spine for kyphoplasty (for use with Cardinal Health Radiopaque Bone Cement).

Summary of Technological Characteristics:

The proposed device and the predicate devices are composed of the same or similar design, materials and manufacturing characteristics.

Summary of testing:

All materials used in the fabrication of the Inflatable Bone Tamp were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". These materials also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use.

Non-Clinical Testing:

Performance testing demonstrated that the proposed device is substantially equivalent to the currently marketed predicate devices with regard to functional characteristics.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL - 1 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cardinal Health
% Ms. Sharon Nichols
1430 Waukegan Road MPKB-3B
McGaw Park, Illinois 60085

Re: K090211

Trade/Device Name: Inflatable Bone Tamp
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: NDN, HRX
Dated: May 29, 2009
Received: June 3, 2009

Dear Ms. Nichols:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

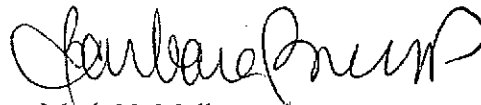
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/cdrh/comp/> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", written in a cursive style.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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Indication for Use

510(k) Number (if known): unknown at this time K090211

Device Name: Inflatable Bone Tump

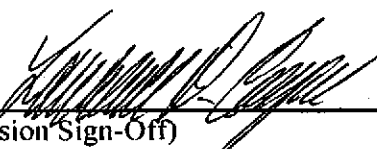
Indications For Use: Intended for the reduction and fixation of fractures in cancellous bone in the spine for kyphoplasty (for use with Cardinal Health Radiopaque Bone Cement).

Prescription Use X or Over-The Counter Use _____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090211

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